FINAL PROGRESS REPORT

A Geofencing-Based Adaptive Messaging System to Support Patient Self-Management of a Low-Sodium Diet in Hypertension

Michael P. Dorsch, PharmD, MS (PI), Larry An, MD (Co-I), Scott L. Hummel, MD, MS (Co-I)

University of Michigan at Ann Arbor

5/3/2016 to 4/30/2019, with one-year no-cost extension

Bryan B. Kim, PhD, Health Scientist / Program Officer, Division of Health Information Technology (IT), Center for Evidence and Practice Improvement (CEPI), Agency for Healthcare Research and Quality (AHRQ)

Acknowledgment of Agency Support: Agency for Healthcare Research and Quality

R21 HS024567

Structured Abstract

Purpose: The objective of the proposed project was to develop actionable push messages that promote adherence to a low sodium diet and will then demonstrate the effectiveness of the mobile application in reducing sodium intake.

Scope: Higher sodium consumption is associated with greater risk of stroke and cardiovascular disease. Interventions that lower sodium intake can decrease blood pressure and improve cardiovascular outcomes. Patients need assistance at grocery stores and restaurants to follow a low sodium diet.

Methods: This research was performed in 2 phases that correlates with the 2 aims. Phase 1 (Aim 1) is a qualitative study to establish an adaptive notification message system for the mobile application and Phase 2 (Aim 2) is a pilot randomized clinical study to determine the effects of the mobile application on surrogate outcomes.

Results: An innovative, personalized, just-in-time mobile application intervention for lowering dietary sodium was created. In a randomized pilot study, several markers of dietary sodium intake and systolic blood pressure were improved by the app compared to control. Self-confidence was not changed by this intervention. Further investigation of this intervention in a larger clinical trial to elucidate the effects of blood pressure is needed in order for widespread adoption.

Key Words: mHealth, Just-in-time interventions, mobile applications, sodium, hypertension, diet

Purpose (Objectives of Study).

The <u>objective of the proposed project</u> was to develop actionable push messages that promote adherence to a low sodium diet and will then demonstrate the effectiveness of the mobile application in reducing sodium intake. The <u>central hypothesis</u> is that a mobile application with geofencing based just-in-time push messages will help hypertensive patients reduce dietary sodium intake and feel more confident in following a low sodium diet. The rationale for this project, supported by the preliminary data, is that patients need immediate information about low sodium dietary options in the places they make most food choices, the grocery store or restaurant. The specific aims were:

- 1. Establish a geofencing based adaptive notification message system for the mobile application using participant feedback to facilitate reducing dietary sodium intake.
- 2. Determine the effectiveness of the newly developed mobile application that provides geofencing based push messages on dietary sodium intake and confidence following a low sodium diet.

Scope (Background, Context, Settings, Participants, Incidence, Prevalence).

<u>Background.</u> High sodium intake is a significant public health problem in the U.S. In a meta-analysis of 177,025 patients, higher sodium consumption was associated with greater risk of stroke (RR 1.23, 95% CI 1.06-1.43) and a trend toward greater cardiovascular risk (RR 1.14, 95% CI 0.99-1.32). Based on 2005 estimates, high dietary sodium is responsible for 102,000 deaths annually. Current federal guidelines advocate a daily sodium intake of less than 2,300 milligrams (mg) with further reduction to 1,500 mg in persons who are 51 and older and those of any age who are African American or have hypertension, diabetes, or chronic kidney disease, while the average sodium intake for all Americans ages 2 years and older is approximately 3,400 mg per day.

Context. Interventions that lower sodium intake can decrease blood pressure and improve cardiovascular outcomes. The sodium-restricted Dietary Approach to Stop Hypertension (DASH) eating plan reduced systolic blood pressure (SBP) by 7.1 mmHg in adults without HTN and 11.5 mmHg in adults with HTN. In an analysis of the Trials of Hypertension Prevention, participants randomized to the low sodium interventions had a 25% lower long-term risk of cardiovascular disease (RR 0.75, 95% CI 0.57-0.99). From 2003 to 2011 in England, the national health survey demonstrated a reduction in sodium intake by 1400 mg per day. During that same timeframe there was a decrease in mortality from stroke by 42% (p<0.001) and ischemic heart disease by 40% (p<0.001) and a reduction in blood pressure by 3±0.33/1.4±0.2 mmHg, which the sodium reduction seen is identified as the likely contributor. From a policy perspective in the United States, reducing sodium intake by 1200 mg per day is projected to prevent 60,000 to 120,000 coronary heart disease events, 32,000 to 66,000 strokes, 54,000 to 99,000 myocardial infarctions and 44,000 to 99,000 deaths from any cause on an annual basis. This reduction in sodium intake would also lead to \$10 billion to \$24 billion savings in the healthcare system.

<u>Setting.</u> For aim 1, we recruited individuals from the University of Michigan Health System to participate in 4 focus groups using the UM Health Research website (https://umhealthresearch.org). For aim 2, we recruited patients from the University of Michigan Health System to participate in this pilot study. Initially recruitment was using the UM Health Research website (https://umhealthresearch.org), but recruitment slowed and we implemented a letter campaign in January 2018, which increased recruitment.

<u>Participants.</u> For aim 1, recruitment began in July 2016 and continued until November 2016. We recruited and consented 27 participants (7 at focus group 1, 8 at focus group 2, 3 at focus group 3 and 9 at focus group 4). For aim 2, recruitment began in July 2017 and continued through January 2019 when the last patient was recruited. We recruited and consented 50 patients. Each subject had an initial visit with a study coordinator for intake in the clinical trial. Those randomized to the mobile application received an educational session on how to use the application.

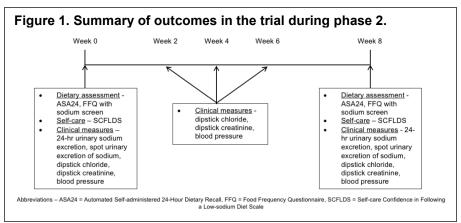
Incidence and Prevalence. Patients need assistance at grocery stores and restaurants to follow a low sodium diet. Over half of Americans consume 1-3 restaurant meals per week and 23% consume ≥ 4 restaurant meals per week. The use of pre-packaged foods in home meal preparation has also increased substantially in recent years. Restaurants and grocery stores are prime targets for intervention with about 77% of all sodium intake in the average U.S. diet coming from processed and restaurant foods. In a recent study on consumer knowledge of sodium intake and food labeling, only half of the over 400 grocery store shoppers were able to accurately use sodium label information to choose low sodium food options. The AHA guideline for the dietary approach

to prevent and treat hypertension states, "any meaningful strategy to reduce salt intake must involve efforts of food manufacturers and restaurants." In a qualitative study using a focus group that included heart failure patients, there three primary themes for nonadherence to low sodium diet: lack of knowledge, interference with socialization and lack of food selections. Many participants in this study felt they needed more detailed information about a low sodium diet. They also expressed frustration in eating out at restaurants stating eating out was an obstacle to adhering to their prescribed diet. Finally, patients stated there are limited choices and poor taste of foods with low sodium content.

Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations).

Study Design. This research was performed in 2 phases that correlates with the 2 aims. Phase 1 (Aim 1) is a qualitative study to establish an adaptive notification message system for the mobile application and Phase 2 (Aim 2) is a pilot randomized clinical study to determine the effects of the mobile application on surrogate outcomes. Phase 1 will be used to take the development of the mobile application from where we are now (concept and prototype) to a developed mobile application. All patients enrolled in the 2 phases of research will be greater than 18 years of age, diagnosed with hypertension, and antihypertensive therapy for at least 3 months. Patients will be excluded if they have chronic kidney disease (CKD), heart failure, SBP >180 mmHg, DBP >110 mmHg or are taking a loop diuretic, corticosteroid, or non-steroidal anti-inflammatory medication. CKD is defined as known kidney damage (structural or functional abnormalities) or estimated Glomerular Filtration Rate (eGFR) less than 60 mls/min/1.73m² (CKD Stage 3, 4, or 5). In Phase 2, participants with an estimated baseline intake of sodium less than 2300mg per day by the Food Frequency Questionnaire (FFQ) will be excluded.

For aim 2, patients were randomized to the mobile application or usual care in a 1:1 fashion. Patients randomized to the mobile application will receive a 30-minute training session about the mobile application and be instructed to use the mobile application for 8 weeks. Figure 1 summarizes the outcomes and time of outcome collection for both groups in our clinical trial.



<u>Data Collection.</u> At focus group 1, participants were asked to take the Self-Care Confidence in Low-Sodium Diet questionnaire and the Dietary Sodium Restriction Questionnaire. We also asked open ended questions about following a low sodium diet and about using a mobile application for lowering sodium intake. At focus group 2, participants were asked open ended questions about following a low sodium diet and about using a mobile application for lowering sodium intake. At focus group 3, participants performed usability testing of the wireframes of the mobile application. At focus group 4, participants were shown each of the 27 messages generated from focus group 2. They were asked if each message was easy to understand, was relevant to them and would motivate them. They were also asked to rate each message overall. These questions used a Likert scale from strongly disagree to strongly agree.

For aim 2, baseline and follow-up data were obtained by University of Michigan staff. Data collection was performed within the mobile application and RedCap surveys. All patients required a baseline FFQ to determine if they met inclusion/exclusion criteria.

<u>Intervention</u>. The intervention with the mobile application includes two parts: 1) just-in-time contextual tailored messages that promote behavior change when a patient enters a grocery store and restaurant; 2) the ability to easily scan and search for the foods at grocery stores and restaurants to find options containing lower sodium content. All messages were personalized based on the participants confidence in following a low sodium diet.

Just-in-time contextual tailored messages are generated based on a multifaceted system. Initially, participants complete the Block Sodium Screener (NutritionQuest) and survey to assess their confidence in following a low sodium diet. The user then created alternatives to the high five sodium containing foods and map these items to locations. In order to properly target messages, we use artificial intelligence algorithms that analyze the changes in mobile phones sensors (including Wi-Fi, Bluetooth, accelerometer, gyroscope, magnetometer, GPS). This takes each individual user's past, recognizes his or her present context and predicts future activity. These predictions then alert the mobile application that the user is entering a grocery store or restaurant. Once the mobile application knows the user's context, the user receives a tailored message based on the context (grocery store or restaurant), their individual high 5 sodium containing foods (from the Block Sodium Screener) and their confidence following a low sodium diet. These messages are delivered by push notifications.

When a user taps on a just-in-time contextual tailored message, the application is opened to the appropriate section for their context, grocery store or restaurant. The grocery store section provides the user with the ability to scan Universal Product Codes (UPC) on food packaging or text search at the grocery store. The mobile application provides feedback on the sodium content of the food using a traffic light signal red (≥ 480mg per serving), yellow (≥ 120mg to < 480mg per serving) and green (< 120mg sodium per serving) to show consumers, at a glappe, whether a product is high modium of

Figure 2. Example of the grocery store result screen for tomato soup using a traffic light signal. 11:06 + ✓ Search items **TOMATO SOUP** 910 mg of sodium per serving One serving has 61% of your daily limit of 1500 BAD LOW SODIUM OPTION Low sodium alternatives Rebecca's Tomato Basil Soun Erin Soup, Tomato, Original Biona Tomato Basil Soup Knorr Instant Soup, Tomato Essential Trading Tomato Soup Suma Tomato Soup Tesco Chunky Soup, Tomato

serving) to show consumers, at a glance, whether a product is high, medium or low in sodium. In addition, the application will list lower sodium options in the same food category (See figure 2). In restaurants, users are presented 3 low sodium meals for that specific restaurant that were curated by the investigators and be able to search the restaurant's menu with items order by sodium content, lowest to highest.

Measures. The Automated Self-administered 24-Hour Dietary Recall (ASA24), developed by the National Cancer Institute for dietary research, will be used to estimate dietary sodium intake during the trial. The ASA24 is an electronic 24-hour recall website that allows patients to self-administer the survey in a user-friendly manner. The ASA24 allows researchers to send the survey at defined intervals and automatically performs a dietary analysis by converting the dietary recall data into nutrient information based on the Food and Nutrient Database for Dietary Studies (FNDDS). In order to provide a detailed interview, the website includes a meal-based quick list, meal gap review, review of forgotten foods, a final review and a question about whether the day's intake was usual or not. We will obtain the sodium content per day from the FNDDS-based sodium content analysis completed by the ASA24 website. The ASA24 will be administered at week 0 and 8 of the study.

The most widely used method for monitoring sodium intake is urinary sodium excretion_measured by a 24-hour urine collection. Patients will be instructed to collect all urine voids for 24 hours and return them for analysis for sodium excretion. Twenty-four hour urine excretion will be collected at baseline and after 8 weeks. This method is not convenient (e.g. difficult to perform collections at work), and some participants may have incomplete urine collections. Because of these challenges, we will also explore other methods to estimate sodium excretion that would be more practical for use in larger trials.

In addition to the gold standard, the first method to estimate 24-hour urinary sodium excretion is spot morning urine excretion of sodium. The Kawasaki formula will be used to estimate 24-hour sodium urinary excretion from a fasting morning urine sample. This approach has been proven to provide a valid estimate of sodium intake in several patient populations and in large-scale epidemiological studies. Participants will be instructed to fast overnight, void in the morning and provide us a second morning urine sample on the day of the assessment. This measurement will be assessed at baseline and after 8 weeks of the study.

Another method for estimating 24-hour urinary sodium excretion is with a spot urine sample using chloride and creatinine dipsticks. The dipstick method has been validated in hypertensive patients and correlates well with 24-hour urinary sodium excretion (r=0.86). The chloride dipstick is used as a surrogate for sodium excretion.

The Quantab chloride dipstick (Hach, Loveland, CO) is placed in a container filled less than half way with urine. The chloride concentration is determined by observation of the change in color from brown to pale on the dipstick, which is the formation of silver chloride. The creatinine dipstick is similar to the chloride dipstick. The MultistixPro-10LS (Bayer, Elkhart, IN) is a dipstick that includes a color pad for creatinine after it is placed in a container filled with urine. The color pad turns from yellow to green to indicate the creatinine concentration. The predicted 24-hour urinary sodium excretion is calculated based on the 24-hour creatinine concentration calculated using sex, weight, race and age. This measurement will be performed at baseline and after week 2, 4, 6 and 8.

The Self-care Confidence in Following a Low-sodium Diet Scale (SCFLDS) will be used to measure the patient's confidence in following a low sodium diet. It assesses the patient's confidence in the ability to select and prepare low-sodium foods. The tool consists of 7 items with 4 response options per item. The items ask the patient to rate their level of confidence reading food labels, choosing low sodium food during shopping, choosing low sodium foods at restaurants, cooking low sodium foods, choosing low sodium foods at relatives or friend's homes, estimating how much sodium the patient eats each day and substituting low sodium foods for high sodium foods. The 4 response options are assigned a score of 1-4 (1=Not confident, 2=Somewhat confident, 3=Very confident, 4=Extremely confident) then added for each question. Possible scores range from 7 to 28 and the higher the score indicates greater confidence. The SCFLDS will be administered at baseline and after week 8 of the study.

Blood pressure were measured on a bi-weekly basis by the patient. Patients were informed to take three blood pressures using standard guideline-based recommendations from the American Heart Association for on how to take a home blood pressure.

Mobile app analytics was collected to determine the extent to which the mobile application was used. This outcome will be key in determining the frequency and intensity of the intervention. We will also collect the Nutritionix API calls to determine the use of the searching functions.

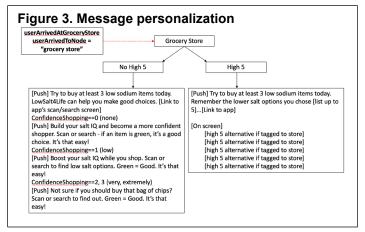
<u>Limitations.</u> This is a small pilot study, which inherently has limitations of generalizability to the general population of HTN patients. Also, the measures of dietary intake are imperfect. Urinary measurements can be altered by one day of sodium intake. Dietary surveys, the FFQ and ASA24, have the limitation of being subjective and requiring recollection of the participants eating habits over a period of time. The study design included an App (Intervention) and No App group (Control) in an unblinded fashion. Participants knew which group to which they were randomized. This could have led to bias in the subjective principle findings.

Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Aim 1: Establish a geofencing based adaptive notification message system for the mobile application using participant feedback to facilitate reducing dietary sodium intake.

Principal Findings. Focus group 1 was held on July 19, 2016 with 7 participants. Participants were asked to take the Self-Care Confidence in Low-Sodium Diet questionnaire and the Dietary Sodium Restriction Questionnaire. We also asked open ended questions about following a low sodium diet and about using a mobile application for lowering sodium intake. We found that hypertensive patients would use a mobile application to help reduce their sodium intake. They are not confident finding low sodium options in restaurants, estimating how much sodium they eat or choosing low sodium foods at friends or relatives houses. Participants usually don't consider sodium content of food when selecting a restaurant, but would like notifications of low sodium options at specific restaurants. Participants are willing to try new foods, eliminate certain foods and change how they prepare foods to lower sodium intake. Participants did not experience physical symptoms from hypertension.

Focus group 2 was held on October 6, 2016 with 8 participants. We asked open ended questions about following a low sodium diet and about using a mobile application for lowering sodium intake. Participants like the ability to create motivational messages for themselves. They thought that scanning items at grocery stores and receiving notifications at restaurants would be a useful way to lower sodium intake. Participants felt that other locations, besides restaurants and grocery stores, should be considered (e.g. home and work). They also felt that the messages could be more personalized to them (adding their name, their locations, their specific top



five foods with alternatives linked to their locations). The personalization of messages is a theme that was discussed by participants at focus groups 1 and 2. We generated a list of messages from this focus group. These messages focused on personalizing the behavioral intervention by location (work, home, grocery store and restaurant) and confidence in lowering their sodium intake. The week of October 10, 2016, we also had 3 focus group participants perform usability testing. They were shown wireframes of the mobile application and gave feedback on the user experience and current flow of the application. Overall, they felt that the flow was adequate and gave small changes on instructions and wording within the

application.

Focus group 3 was held on November 1, 2016. Nine participants were shown each of the 27 messages generated from focus group 2. They were asked if each message was easy to understand, was relevant to them and would motivate them. They were also asked to rate each message overall. These questions used a Likert scale from strongly disagree to strongly agree. Most participants strongly agreed or somewhat agreed that all the messages were clear, relevant and motivating. The message "Portion size matters! Eating less than a full portion is a great way to cut back on salt" was viewed negatively. An alternative that participants decided on was "Ask for a doggie bag right away to be sure you only eat a smaller portion." Participants found the following message to be very helpful "Eating out just got easier. Remember to order one of the low salt options [Link to app]." Users also gave us feedback on the green/yellow/red stoplight idea. They recommended using a smiley face and grumpy face along with the colors so users u understood them better. From this focus group, the final list of messages was developed (Figure 3).

Aim 2: Determine the effectiveness of the newly developed mobile application that provides geofencing based push messages on dietary sodium intake and confidence following a low sodium diet.

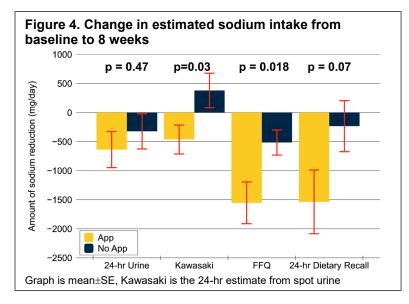
Principal Findings. Fifty patients were enrolled and randomized in the clinical trial (24 App, 26 No App). There were no significant differences between the two groups, except SCFLDS. The mean age was 57±10 years in the App group ad 58±11 years in the No App group (p=0.58) and baseline systolic blood pressure was 129±4 mmHg in the App group and 128±4 mmHg in the No App group. Measures of sodium intake at baseline were similar between the two groups. All baseline

Table 1. Baseline demographics App (N=24)P-value Variable No App (N=26) 57 ± 10 58 ± 11 0.58 Age (years) Female 14 (58) 16 (61) 0.82 0.22 Previous MI 2 (8.3) 0(0)DM 0(0)1(3.9)1.0 Stroke or TIA 0(0)1(3.9)1.0 Systolic BP, mmHg 129 ± 3.8 128 ± 3.5 0.22 SCr, mg/dL 0.88 ± 0.1 0.89 ± 0.2 0.90 3607 ± 1755 24-hr urine sodium, mg 3561 ± 1924 0.93 FFQ sodium, mg/day 3995 ± 2119 3660 ± 1314 0.51 ASA24 sodium, mg/day 5127 ± 3118 3877 ± 1773 0.09 Sodium Screener, points 30.3 ± 11 31.4 ± 8 0.70 SCFLDS, points 20.9 ± 5 18.4 ± 3 0.04 Data represented as mean±SD or N (%), as appropriate.

measurements are represented in table 1.

Sodium Intake. Patients had a greater reduction of sodium intake, by both subjective and objective measurements, in the App group compared to the No App group at 8 weeks. See Figure 4 for the change in estimated sodium intake from baseline to 8 weeks. In addition to the estimated sodium intake, patients had a greater reduction in the sodium screener score in the App group compared to the No App group over the 8 weeks (App -9.5 ± 9 vs. No App -4.7 ± 9 , p=0.07).

SCFLDS. At baseline, participants in the App group were more confident at following a low sodium diet. Over time, there was no difference in the change in confidence between the two groups. Confidence following a low sodium diet did not change from baseline to follow up in the App group (Score change 0.08, p=0.93). In the No



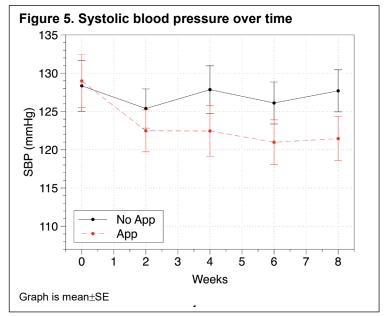
App group, confidence following a low sodium diet decreased over the 8 weeks, but with unclear statistical and clinical significance (Score change -1.08, p=0.17). Analysis of the individual questions did not demonstrate a change in confidence reading food labels, shopping at grocery stores or choosing low sodium options at restaurants.

Blood Pressure. Patients in the App group had a greater reduction in systolic blood pressure over time compared to the No App group (group by time interaction p=0.38). The largest reduction difference between the two groups in systolic BP was at week 8 (App -7.5 vs. No App -0.7 mmHg, p=0.12). Figure 5 demonstrates the change in systolic blood pressure over time.

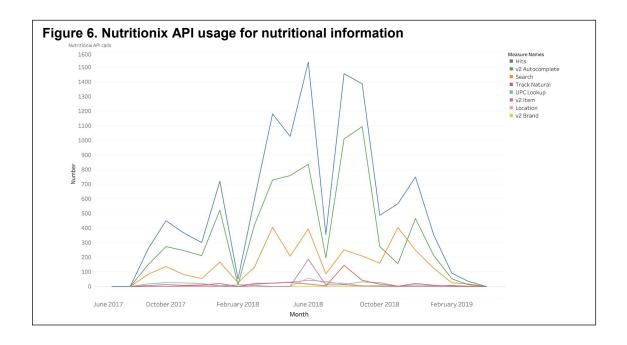
Mobile Application Analytics. Patients received push notifications on a regular basis and used the nutrition information in the mobile application. Over the eight weeks of the study, patients received a median of 126 (IQR 75, 186) push notifications; 6 (IQR 3, 12) while arriving at the grocery store, 41 (IQR 9, 60) while arriving

at a restaurant, and 73 (IQR 37, 96). Females were more likely than males to receive a notification when arriving at a grocery store (7.5 [4, 15] vs. 3 [1, 9], Wilcoxon p=0.068). There was no appreciable difference in the number of notifications to females versus male at restaurants (41 [9, 60] vs. 34 [4, 61], Wilcoxon p=0.70).

Figure 6 shows the Nutritionix API calls from the mobile application over the course of the clinical trial. This demonstrates a significant usage of the nutrition information within the mobile application. "Hits" represents the overall number of API calls, which reached a height at 1535 hits in June 2018. "Autocomplete" represents a search when typing in the application, which reached 836 searches in June 2018. "UPC Lookup" is the scanning function in the application. UPC lookup was used 20-40 times per month during the clinical trial.



Patient Survey. At the end of the study we performed a survey of the patients that received the mobile application to elicit their opinion on the dietary sodium intervention. Of the 24 patients, 79.2% agreed that the app was useful, 79.2% agreed the information from the app was useful in my daily life, 70.8% agreed that the information they received in the app was important to them. One participant (4.2%) disagreed that the app was easy to use, 1 participant agreed the app was difficult to understand, 3 participants (12.5%) agreed the app was confusing, and 1 participant disagreed that most people would learn to use the app very quickly. Eleven (45.8%) felt like the app gave them just the right amount of information, while 8 participants (33.3%) felt there was less information than they wanted and 3 (12.5%) felt there was more information than they needed. Thirteen (59.1%) felt that the number of notifications was the right amount, while 5 (22.7%) felt there were too few and 3 (13.6%) felt there were too many notifications.



Outcomes.

- Patients expressed the need for personalization for the push notifications.
- A list of 27 messages were created and implemented in the final mobile application studied in Phase 2.
- These messages were personalized based on location, confidence in following a low sodium diet and patient-selected alternatives to high sodium containing foods in their. See figure 3 for an example.
- The mobile application based just-in-time contextual dietary sodium intervention reduced both subjective and objective measurements of sodium intake compared to the control group over time, even though not all measurements were statistically significant.
- The intervention did not improve patient confidence following a low sodium diet.
- We have also shown that the intervention improves a new sodium screener and systolic blood pressure over the 8-week study.
- The mobile application analytics demonstrates that participants received the notifications and used the application for nutrition information.
- Overall patients that received the intervention thought it was useful and agreed that the information provided was important to them.
- Patients also felt that the app was easy to use and that more people could learn to use the app very quickly.

Discussion.

We have demonstrated in a pilot study that a just-in-time dietary sodium intervention within a mobile application can improve subjective and objective measurements of dietary sodium intake and systolic blood pressure compared to a control group. While some of the reductions were not statistically significant, the small study showed clinically meaningful reductions in all of these endpoints. This supports the next step being a larger randomized clinical trial.

Interestingly, the patients' confidence in following a low sodium diet was not affected by the intervention. Even when investigating specific questions from the survey about grocery stores and restaurants, there was difference between groups. This supports the theory that the intervention does not affect patient self-confidence. It could also be that patients require a longer duration of the intervention in order to feel more self-confident. Our intervention period was relatively short, only 8 weeks.

There are several limitations to our study. Due to the clinically relevant reductions in measurements of sodium intake, it is clear we were underpowered to detect a difference in the main outcomes. Furthermore, there were baseline differences in confidence in following a low sodium diet. It is unclear if this difference in confidence is clinically significant, but nevertheless future research should further investigate this finding. Lastly, the clinical trial was set up as an App versus No App study where the control group did not receive the application. This could have led to several biases at the patient level. Patients could have felt left out of the intervention arm and

not engaged enough in the study. While we did not see this in the study population, it could have been present. Future studies should be organized so that both groups receive an application and feel receive some level of support in the application control group.

Conclusions.

An innovative, personalized, just-in-time mobile application intervention for lowering dietary sodium was created. In a randomized pilot study, several markers of dietary sodium intake and systolic blood pressure were improved by the app compared to control. Self-confidence was not changed by this intervention. Further investigation of this intervention in a larger clinical trial to elucidate the effects of blood pressure is needed in order for widespread adoption.

Significance.

An easy to use mobile application-based dietary sodium intervention could dramatically reduce sodium intake, thus reducing blood pressure and subsequent cardiovascular events.

Implications.

The effects of a mobile application on subjective and objective measurements of sodium intake has far reaching implication on dietary adherence as whole. Further research should focus on this type of interventions effect on a whole host of diseases and dietary patterns. In addition, research should begin to integrate how providers could prescribe this type of intervention for patients so that outcomes can be improved.

List of Publications and Products.

- 1. Dorsch MP and Hummel SL. (2017). LowSalt4Life (version 1) [Computer Software]. Ann Arbor, MI: University of Michigan. Available from https://itunes.apple.com/us/app/lowsalt4life/id1273864294?mt=8.
- 2. **Dorsch MP**, An LC, Hummel SL. A randomized controlled trial evaluating a novel just-in-time contextual mobile application intervention to reduce sodium intake in hypertension: Design and rationale for the LowSalt4Life trial. *JMIR Res Protoc.* 2018;7(12):e11282.